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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,152	08/24/2005	Beatriz Perez Esteban	13566.105017	1501

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KING & SPALDING  
1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036-4003

EXAMINER
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MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,152	<b>Applicant(s)</b> ESTEBAN ET AL.	
	<b>Examiner</b> Maryam Monshipouri	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

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|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>filed 1/2007</u> . | 6) <input type="checkbox"/> Other: ____  |

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Applicants' arguments filed on 1/25/07, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Claims 2-6 have been canceled. Claims 1, 7-12 are still at issue and are present for examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1(a), 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "wherein said modification, variant or fragment is capable of hybridising to the complement of SEQ ID NO:1" in claim 1 is redundant. A variant of SEQ ID NO:1 having at least 95% or more identity to SEQ ID NO:1 is by inherency capable of hybridising to the complement of SEQ ID NO:1, therefore it is unclear how said phrase provides any additional information about the invention. Claims 10-12 are merely rejected for depending from a rejected base claim 1.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7-12 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention according to previous office action. In traversal of this argument applicant argues that he/she has amended the claims and instantly claimed sequences are capable of hybridising to a defined set of sequences, which is a function for the claimed sequences.

This argument was fully considered but was found **unpersuasive**. This is because applicant in none of the above claims has recited any function for the claimed products. Even though phrases such as "hybridizing to a full-length sequence expression product encoding sequence " (see claims 1, 7) may provide some additional structural information about the claimed invention (at least for claim 7) ; they fail to provide any function for the claimed polynucleotides. More specifically, as mentioned previously, a **genus** of isolated DNA sequence that has 95% or higher identity to SEQ ID NO:1 and can hybridise to SEQ ID NO:1 is capable of encoding a genus of products with to totally different functions than the function of SEQ ID NO:1 expression product (a **single species**).

This lack of written description is even more pronounced in claims 8-9, wherein the structural limitations of DNA fragments and probes, which have no function is even less than those of claim 1((a) and claim 7. In claim 8, applicant is reciting a **genus** of products comprising merely 5-30 nucleotides of SEQ ID NO:1 or homologs thereof, which are capable of hybridizing to said sequence or homologs thereof, with no specific function. Supposing, for the sake of argument said genus embraces a DNA sequence

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species of, for example, 3000 base pairs, only 30 of which matching SEQ ID NO:1. Such sequence may even hybridise under certain conditions to SEQ ID NO:1, but such DNA sequence is almost certainly not going to encode a product similar to 16S ribosomal RNA of this invention and therefore the genus of claimed probes and fragments of claims 8-9 remain rejected for lack of adequate structure and function.

Since products of claim 1 are inadequately described, bacteria comprising said products (claims 11-12) are also inadequately described.

Claims 1, 7-12 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated DNA sequences consisting of or comprising SEQ ID NO:1 does not reasonably provide enablement for either SEQ ID NO:1 variants and homologs having at least 95% identity to SEQ ID NO:1 or fragments and probes comprising at least 5 or more bases of SEQ ID NO:1 or claimed homologs thereof wherein said fragments or probes are capable of hybridizing to SEQ ID NO:1 or claimed homologs thereof, according to previous office action. In traversal of this rejection applicant relies on the same arguments provided above, which have already been addressed above.

Since SEQ ID NO:1 homologs of Claim 1(a) are not fully enabled bacteria comprising them (claims 11-12) are not fully enabled either.

**No claim is allowed.**

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Monshipouri

Maryam Monshipouri Ph.D.

Primary Examiner

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